TB-500 (Thymosin Beta-4 Fragment) — Research Summary

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1. What It Is

TB-500 is commonly sold as a synthetic, N-terminal-acetylated 17-amino acid fragment of the naturally occurring 43-amino-acid protein thymosin beta-4 (Tβ4), covering the actin-binding domain of the parent molecule (sequence: Ac-LKKTETQ-OH region). Thymosin beta-4 is expressed in nearly all animal cell types and plays a role in cytoskeletal organization via actin sequestration.

Important distinction: Most published human clinical trial data exists for the full-length 43-amino-acid Thymosin Beta-4 protein — not specifically for the shorter 17-amino-acid TB-500 fragment sold under that name. This distinction matters for interpreting the evidence base below.

- **Regulatory note:** As of 2026 discussions, TB-500 (as the thymosin beta-4 fragment, sequence LKKTETQ) has been named among FDA 503A Category 2 bulk drug substances under compounding review — check current status before referencing in customer materials. TB-500-class peptides are also on the WADA Prohibited List (Section S2), relevant for customers in tested athletic contexts.
- **PCAC update (July 23, 2026):** The FDA's Pharmacy Compounding Advisory Committee voted 8–6 (one abstention) to recommend TB-500 for inclusion on the 503A Bulk Drug Substances List, overriding FDA staff's own recommendation against inclusion. This is a non-binding advisory recommendation only — it does not add TB-500 to the list, does not authorize compounding, and does not change RUO sale status. A formal rulemaking process, expected to take 8–12 months, would be required before any actual change takes effect.

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2. Reported Effects in Research Literature

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Preclinical (TB-500 fragment and full-length Tβ4): - Reported to enhance cellular migration and cytoskeletal remodeling via actin-sequestering activity. - Preclinical wound-healing studies report accelerated healing and organized connective tissue repair, with reduced myofibroblast formation. - Animal studies report reduced inflammation and faster healing markers in cardiac and skeletal muscle injury models.

Human evidence — mostly from full-length Thymosin Beta-4, not TB-500 specifically: - Full-length Tβ4 has progressed to human Phase 2 trials for chronic wounds (pressure ulcers, venous stasis ulcers), with reported accelerated healing rates and good tolerability versus standard care. - Ophthalmic Phase 2 trials of full-length Tβ4 for dry eye syndrome and neurotrophic keratopathy have reported positive signals. - A Phase I safety trial of synthetic Thymosin Beta-4 (doses 42–1,260 mg over 14 days) reported no toxicity or serious adverse events. - A separate, related compound — recombinant human Thymosin Beta-4 (NL005) — recently completed a Phase IIb trial (NCT05984134) for acute myocardial infarction. - As of 2026, a scoping review of 1,772 records (80 included studies) found the evidence base for tissue healing/musculoskeletal repair was weighted toward mixed and in vitro designs, with most studies evaluating full-length Tβ4 rather than the shorter TB-500 fragment; no completed, published human RCTs exist specifically for TB-500 for any indication.

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3. Clinical & Preclinical Study References

- Ehrlich HP, Hazard SW 3rd. "Thymosin beta4 enhances repair by organizing connective tissue and preventing the appearance of myofibroblasts." *Ann N Y Acad Sci*. 2010;1194:118-24. PMID: 20536458
- Malinda KM, Sidhu GS, Mani H, et al. "Thymosin beta4 accelerates wound healing." *J Invest Dermatol*. 1999;113(3):364-8.
- Scoping review: "Thymosin Beta-4 and TB-500 in Tissue Healing, Regeneration, and Musculoskeletal Repair." *MDPI, 2026* — full text
- Related compound Phase IIb cardiac trial: NCT05984134 — Efficacy and Safety of NL005 (Recombinant Human Thymosin β4) in Acute Myocardial Infarction

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4. Reconstitution Process

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Keep out of reach of children. Not for use by pregnant or nursing individuals. For laboratory research use by qualified personnel only.

1. **Materials needed:** lyophilized (freeze-dried) TB-500 powder, bacteriostatic water, alcohol swabs, syringe with needle.
2. **Bring the vial to room temperature** before reconstitution.
3. **Sanitize** the rubber stopper of both vials with an alcohol swab.
4. **Draw the bacteriostatic water** into the syringe.
5. **Add the water slowly** down the *inside wall* of the vial rather than directly onto the powder, to reduce shear/foaming.
6. **Do not shake.** Gently swirl or roll between palms until fully dissolved.
7. **Inspect the solution** — should be clear and free of particulates.
8. **Label the vial** with reconstitution date and concentration.
9. **Storage:** refrigerate (2–8°C); avoid freeze-thaw cycles.

Reference: Bacteriostatic Water Volume by Vial Size

Vial Size	BAC Water Added	Resulting Concentration
5 mg	1 mL	5 mg/mL
5 mg	2 mL	2.5 mg/mL
5 mg	5 mL	1 mg/mL
10 mg	1 mL	10 mg/mL
10 mg	2 mL	5 mg/mL
10 mg	4 mL	2.5 mg/mL
10 mg	5 mL	2 mg/mL
10 mg	10 mL	1 mg/mL

Notes: Higher water volume = more dilute solution; lower volume = more concentrated. Follow supplier COA fill-line guidance where provided. Always use bacteriostatic water (0.9% benzyl alcohol) for multi-draw vials; sterile water without preservative should be discarded within 24 hours of reconstitution.

Document created: July 16, 2026. **Revision 1:** July 29, 2026. Regulatory status (FDA compounding lists, WADA lists) is actively shifting; re-verify against current sources before any customer-facing use.
